

510(k) Summary of Safety and Effectiveness

August 26, 2000

Submitter

Protocol Systems, Inc.
8500 S.W. Creekside Place
Beaverton, OR 97008-7107
USA

Telephone: (503) 526-8500
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Contact: Mr. Don M. Abbey, Vice President, Quality Systems

Device Name

Trade Name: Micropaq™ vital signs monitor, models 402 and 404
Common Name: Cardiac Monitor
Classification Name: Cardiac Monitor (Reference, 21CFR870.2300, April 1, 1999). The Micropaq model 404 also contains a Pulse Oximetry (SpO₂) channel (Reference, 21CFR870.2700, April 1, 1999).
Classification: Class II

Predicate Device

The predicate device is the Criticare System, Inc. MPT® 2.4 Multiple Parameter Telemetry (K961223).

Device Description

The Micropaq is a patient wearable device that provides real time monitoring and display of ECG and SpO₂. The Micropaq is powered by a rechargeable battery and has a liquid display (LCD) that displays both waveforms and numerics. The Micropaq can communicate with Protocol Systems' Acuity® central station through a wireless local area network (WLAN) operating in the ISM 2.4 GHz band. The communication link is bi-directional, providing monitoring at the Acuity central station and remote control of the Micropaq from the Acuity central station.

Indications for Use

The Micropaq monitor is intended to be used by clinicians for single or multiparameter vital signs monitoring of ambulatory and non-ambulatory pediatric and adult patients in health care facilities. It is also intended for patient transport. Micropaq is intended to operate with an Acuity® central station through wireless communication over Protocol's FlexNet™ network. FlexNet connects multiple devices through hardwired Ethernet networks and Wireless Local Area Networks (WLANs) to an Acuity® central station. If the Micropaq is moved out of range or loses communication with the FlexNet network, it continues to monitor the patient, display patient data, and generate local patient alarms or alert messages.

- The ECG channel is intended for five-lead ECG monitoring.
- The Pulse Oximetry channel is intended for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate (measured by an SpO₂ sensor).

The most likely locations for patients monitored by this device are step-down units, telemetry departments, general med/surg floors, emergency departments, and in-hospital transport. This device is available for sale only upon the order of a physician or licensed health care profession.

Technological Comparison to the Predicate Device

It is Protocol's conclusion that the Micropaq vital signs monitor and WLAN connection to the Acuity central station is substantially equivalent to the Criticare Systems, Inc. MPT® 2.4 Multiple Parameter Telemetry and RF link to their VitalView™2.4 Central Station.

- The ECG specifications and performance are equivalent.
- The SP02 specifications and performance are equivalent.
- Both devices use a liquid crystal display (LCD) to display patient waveforms and numerics.
- The communication link is equivalent. Both systems use digital Frequency Hopping Spread Spectrum operating in 2.4 GHz ISM Band supplied by the same manufacturer. This has proven to be a reliable RF communication link.
- The MPT® 2.4 provides alarm annunciation at the central station. The Micropaq provides alarm annunciation at both the monitor and central station.
- The battery technology used in both devices is equivalent. The Micropaq uses lithium ion batteries. The MPT® 2.4 uses nickel metal hydride batteries. Lithium ion technology is very common and may provide some improvement in operating time.

Summary of Performance Testing

The Micropaq and associated accessories have been tested and found to comply with the recognized, national and international, performance, safety, and electromagnetic compatibility standards for medical devices and product specifications listed in the Micropaq labeling.

A risk analysis, identifying potential hazards and documenting mitigation of the hazards, has been developed and verified/validated as part of Protocol Systems' product development procedures. Protocol Systems' Quality System conforms to 21CFR820 and certified by TUV Product Service to ISO 9001 and EN46001.

Conclusions

As stated above, Protocol's conclusion is that the Micropaq vital signs monitor and WLAN connection to the Acuity central station is safe, effective, complies with the appropriate medical device standards, and is substantially equivalent to the Criticare Systems, Inc. MPT® 2.4 Multiple Parameter Telemetry and RF link to their VitalView™2.4 Central Station.

This 510(k) Summary of Safety and Effectiveness may be copied and submitted to interested parties as required by 21CFR807.92.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 21 2000

Mr. Don M. Abbey
Vice President, Quality Systems
Protocol Systems, Inc.
8500 S.W. Creekside Place
Beaverton, OR 97008-7107

Re: K002725
Micropaq Vital Signs Monitor, Models 402 and 404
Regulatory Class: II (two)
Product Code: 74 DRT
Dated: August 29, 2000
Received: August 31, 2000

Dear Mr. Abbey:

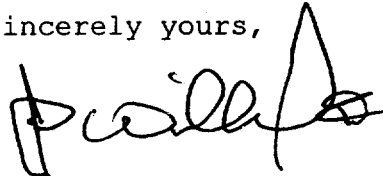
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4645. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "J. Dillard III", with a large, stylized initial "J" and a long horizontal stroke extending to the right.

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosures

INDICATIONS FOR USE

Applicant:

Protocol Systems, Inc.
8500 S.W. Creekside Place
Beaverton, OR 97008-7107
USA

Telephone: (503) 526-8500

Fax: (503) 526-4200

510(k) Number: _____

Device Name: Micropaq™ vital signs monitor, models 402 and 404

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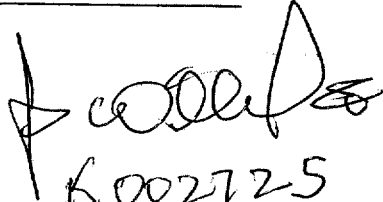
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter _____
(Per 21 CFR 801.109)


K002725